



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 522, and 529

[Docket No. FDA-2017-N-0002]

New Animal Drugs; Withdrawal of Approval of a New Animal Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) and an abbreviated new animal drug application (ANADA) at the sponsors' requests because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5761, [sujaya.dessai@fda.hhs.gov](mailto:sujaya.dessai@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: The sponsors of the following applications have requested that FDA withdraw approval of the NADA and ANADA listed in the following table because the products are no longer manufactured or marketed:

File No.	Sponsor	Product Name	21 CFR Section
135-773	Baxter Healthcare Corp., One Baxter Pkwy., Deerfield, IL 60015	AERRANE (isoflurane USP)	529.1186
200-421	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045	Ceftiofur (ceftiofur Na) for Injection	522.313c

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 Notice of withdrawal of approval of application (21 CFR 514.116), notice is given that approval of NADA 135-773 and ANADA 200-421, and all supplements and amendments thereto, is hereby withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Elsewhere in this issue of the Federal Register, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: February 23, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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